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No. 04-695

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

HOUSEY PHARMACEUTICALS, INC.,
Petitioner,

v.

ASTRAZENECA UK LTD., *et al.*,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the court of appeals properly agreed with the district court's construction of a disputed claim term common to petitioner's patents, and accordingly affirmed the district court's judgment that the patents are invalid and not infringed.

CORPORATE DISCLOSURE STATEMENT

The following are parent companies of, or publicly held companies that own 10% or more of the stock of, respondents AstraZeneca UK Ltd., AstraZeneca LP, and AstraZeneca Pharmaceuticals LP: AstraZeneca PLC, AstraZeneca Treasury Ltd., and AstraZeneca AB.

The following are parent companies of, or publicly held companies that own 10% or more of the stock of, respondent Aventis Pharmaceuticals, Inc.: Sanofi-Aventis, Aventis SA, Aventis Inc., Aventis Holdings Inc., Aventis Beteiligungsverwaltung GmbH, Aventis Pharma SA, Aventis Investissement, and Aventis Pharma Holdings GmbH.

Bristol-Myers Squibb Company has no parent company, and no publicly held company holds 10% or more of its stock.

Merck & Co., Inc., has no parent company, and no publicly held company holds 10% or more of its stock.

Wyeth Pharmaceuticals, Inc., is a wholly-owned subsidiary of Wyeth. Wyeth has no parent company, and no publicly held company holds 10% or more of its stock.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-22a) is reported at 366 F.3d 1348. The order of the district court (Pet. App. 23a) entering a stipulated judgment holding petitioner's patents invalid and not infringed on the basis of claim constructions adopted after a joint hearing in this case and *Bayer AG* v. *Housey Pharmaceuticals, Inc.*, Civ. No. 01-148-SLR (D. Del.), and the claim construction order formally entered in *Bayer* (Pet. App. 30a-32a), are not reported. The district court's later opinions in *Bayer* holding the same patents unenforceable because of Dr. Housey's inequitable conduct during their prosecution, and awarding Bayer $1.8 million in attorneys' fees, are not officially reported, but they are available at 2003 WL 22953187 and 2004 U.S. Dist. LEXIS 9633, respectively.

STATEMENT

This is one of a number of cases involving four patents obtained by Gerard Housey and assigned to petitioner Housey Pharmaceuticals, Inc. The patents purport to cover methods for pharmaceutical research. The litigation has not gone well for petitioner.

1. In the first of two proceedings relevant here, Bayer AG and its U.S. affiliate Bayer Corporation sued petitioner for a judgment declaring the Housey patents invalid, unenforceable and not infringed. *See Bayer AG* v. *Housey Pharms., Inc.*, 169 F. Supp. 2d 328, 328 (D. Del. 2001). The district court rejected one of petitioner's theories of infringement (based on 35 U.S.C. § 271(g)) as a matter of law. *Id.* at 330-331. The court later entered final judgment on that issue under Fed. R. Civ. P. 54(b), and the Federal Circuit affirmed. *Bayer AG* v. *Housey Pharms., Inc.*, 340 F.3d 1367, 1370, 1378 (Fed. Cir. 2003).

While that infringement decision was on appeal, the district court consolidated *Bayer* with the present case for purposes of construing disputed claim language in the patents. *See* Pet. App. 2a n.1. Its construction led, as petitioner stipulated, to the conclusion that the patents are invalid and not infringed. *Id.* at 30a-32a (claim-construction order), 24a-29a (stipulation).

The court later conducted a four-day trial in *Bayer* to decide whether Dr. Housey had engaged in "inequitable conduct" while prosecuting his patents before the Patent and Trademark Office (PTO). The court concluded that Housey's conduct showed "a pattern of behavior inconsistent with [his] duty of candor" to the PTO; that his testimony before the court was not credible; and that Bayer had proven by clear and convincing evidence that Housey never performed experiments that he described in his patent applications and relied on in overcoming an initial rejection by the patent examiner. *Bayer AG* v. *Housey Pharms., Inc.*, No. Civ-01-148-SLR, 2003 WL 22953817, ¶¶ 109, 115-116 (D. Del. Dec. 4, 2003) (*Bayer III*), *appeal pending*, No. 04-1194 (Fed. Cir.) (argued Nov. 3, 2004). Because "[i]ntentionally misrep-

resenting key experiments to the PTO is conduct which cannot be explained, defended nor excused," the court held that, under established law, Housey's inequitable conduct during the prosecution rendered all four of his patents unenforceable. *Id.* ¶ 117. In a separate order, the court held that Bayer's case was an "exceptional" one within the meaning of 35 U.S.C. § 285, and exercised its discretion to order petitioner to pay Bayer $1.8 million in attorneys' fees. *Bayer AG* v. *Housey Pharms., Inc.*, No. 01-148-SLR, 2004 U.S. Dist. LEXIS 9633 (D. Del. May 4, 2004) (*Bayer IV*), *appeal pending*, No. 04-1403 (Fed. Cir.) (argument scheduled for Jan. 13, 2005).

2. In the present proceeding, petitioner sued respondents and others in the same district court in which *Bayer* was pending, alleging that respondents were infringing the same four patents. Pet. App. 2a.[1] As noted above, the court consolidated the two cases solely for purposes of construing the patent claims. *See id.* at 2a n.1. Based on its construction of the claim term "inhibitor or activator of a protein," and petitioner's stipulation about the effect of that construction, the court held the patents invalid and not infringed. *Id.* at 2a, 23a.[2]

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[1] The petition names Roche Holdings, Inc., Hoffman-La Roche Inc., Roche Laboratories, Inc., and Syntex (U.S.A.) Inc. as respondents. Those entities settled with petitioner while this case was pending in the Federal Circuit, and stipulated to dismissal of the appeal (and a cross-appeal) as to them. The court of appeals denied the motion on the ground that there was no separately-docketed proceeding that could be dismissed, but it revised the official caption of the case "to reflect that Roche will not be participating in this appeal." C.A. Order of Mar. 5, 2003, at 2 (Fed. Cir. No. 03-1193); *see* Pet. App. 1a (listing Roche entities as "defendants" but not as "appellees" or "cross-appellants"). The Roche entities accordingly ceased to be parties in the court below, are not proper respondents in this Court, and in any event would appear to "have no interest in the outcome of the petition." S. Ct. Rule 12.6.

[2] Based on its construction of the term "phenotypic characteristic," and petitioner's stipulation about the effect of that construction, the court also held the patents not infringed by the AstraZeneca, Merck, and Bristol-Myers respondents. *See* Pet. App. 25a-26a. The Federal Circuit did

The Federal Circuit affirmed. Pet. App. 1a-22a. In particular, the court rejected petitioner's argument that the term "inhibitor or activator of a protein" (*id.* at 9a), read in the context of the other claim language, the patent specification, and the prosecution history, should be limited to substances that inhibit or activate a protein's biological activity in a particular way—*i.e.*, by binding directly to it. *Id.* at 8a-13a. Among other points, the court noted that "the word 'bind' or 'binding' appears nowhere in the '281 patent in conjunction with" the disputed claim term. *Id.* at 9a. Similarly, it rejected petitioner's reliance on "the recurring presence of the terms 'specific' and 'specifically' in the specification and the prosecution history," both because they gave rise to no strong inference of a direct-binding limitation, and because of "the absence of the word 'specific' in the claim language [itself] (and [the court's] repeated warnings not to import limitations from the specification that are not present in the claims[.]" *Id.* at 11a-12a.

Judge Newman dissented, generally arguing that the majority should have placed less weight on the plain meaning of terms used in the patent claims. Pet. App. 15a-19a. Focusing on the word "specificity" (although that word does not appear in the claims), Judge Newman considered the patents ambiguous on their face, and the technical evidence conflicting. *Id.* at 19a-22a. She would have remanded the matter to the district court for further claim-construction proceedings. *Id.* at 22a.

The full court denied petitioner's request for rehearing *en banc*, without recorded dissent. Pet. App. 33a-34a.

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not find it necessary to address the construction of "phenotypic characteristic."

ARGUMENT

Petitioner devotes much of its submission to rearguing the merits of its proposed claim construction, which has been rejected by both the district court and the Federal Circuit. *See* Pet. 1-12, 22-30.[3] Ultimately, however, petitioner does not ask this Court to review that patent-specific question. Instead, it argues (Pet. 14) that "[c]onflicts among Federal Circuit decisions establish the need for clarification of the proper approach to construing patent claims."

As petitioner notes (Pet. 15-17), however, the Federal Circuit itself recently granted *en banc* review in a different case in order to address that very question. *See Phillips* v. *AWH Corp.*, 376 F.3d 1382 (Fed. Cir. 2004) (*per curiam*) (*en banc*). Once the Federal Circuit has decided *Phillips*—with the benefit of "the roughly three dozen amicus briefs, including one by the United States, that have been filed to address these fundamental questions" (Pet. 17)—this Court will have ample opportunity to consider whether it should review, either in *Phillips* or in a later case, whatever approach the Federal Circuit adopts. In the meantime, there is no reason for the Court to delay resolution of the present case.[4]

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[3] For present purposes we see no need to respond to petitioner's arguments on the merits. We note, however, that while patent holders typically seek expansive readings of their claims, here petitioner seeks to distinguish prior art and avoid invalidity by importing into the claims an unstated limitation requiring that the "inhibitor or activator of a protein" identified by the claimed methods must act by binding directly to the protein. Yet, as the court of appeals pointed out, "[t]he word 'bind' or 'binding' appears nowhere in the [representative] patent in conjunction with an 'inhibitor or activator of a protein.'" Pet. App. 9a; *see also id.* at 12a ("specific" does not appear in claim language). Petitioner characterizes the construction adopted by both courts below as "bizarre[]" and senseless. Pet. 13. Yet even Judge Newman, although critical of the majority's approach, did not accept *petitioner's* claim construction. *See* Pet. App. 19a-22a. She concluded only that the claims were ambiguous, and would have "remand[ed] for resolution of conflicting scientific evidence." *Id.* at 22a.

[4] The Federal Circuit granted *en banc* review in *Phillips* on July 21, 2004. 376 F.3d at 1382. Petitioner's request for rehearing *en banc* in this case was filed on May 21, 2004, and denied on August 25, 2004. *See* Pet.

There is, moreover, a further consideration, not noted in the petition. As explained above (at 2-3), in the parallel *Bayer* proceeding, the same district court that decided this case also found, after a four-day trial and applying the clear-and-convincing-evidence standard, that in obtaining the patents at issue here Dr. Housey made "material misrepresentations [to the PTO] regarding experiments he claimed to have conducted," "knowingly withheld prior art," and "engaged in a pattern of concealment inconsistent with the duty of candor" on the part of patent applicants. *Bayer IV*, 2004 U.S. Dist. LEXIS 9633, at *2-3 (attorneys' fees decision, describing earlier findings); *see Bayer III*, 2003 WL 22953187, ¶¶ 94-117. Based on those findings, the court applied the inequitable conduct doctrine and held all four patents unenforceable. *Bayer III*, 2003 WL 22953187, ¶ 117; *see, e.g.*, *Precision Instrument Mfg. Co.* v. *Automotive Maint. Mach. Co.*, 324 U.S. 806, 814-820 (1945); *Dayco Prods., Inc.* v. *Total Containment, Inc.*, 329 F.3d 1358, 1362-1364 & n.3 (Fed. Cir. 2003) (discussing doctrine).

The inequitable conduct decision in *Bayer III* is currently on appeal. *Bayer AG* v. *Housey Pharms., Inc.*, No. 04-1194 (Fed. Cir.) (argued Nov. 3, 2004).[5] Unless the Federal Circuit reverses the district court's holding that the patents are unenforceable, any dispute about the proper construction of the patents' claims is moot. Accordingly, this case would not be an appropriate vehicle for review of general claim-construction principles by this Court, even if

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App. 34a; C.A. Docket (No. 03-1193). The court of appeals accordingly had ample opportunity to evaluate this case as a vehicle for addressing general claim-construction issues, and chose instead to grant review in *Phillips*. Moreover, the Federal Circuit evidently saw no reason to hold this case pending its decision in *Phillips*. *Cf. Novartis Pharms. Corp.* v. *Eon Labs Mfg., Inc.*, No. 03-1211 (Fed. Cir.) (petition for rehearing *en banc* filed Apr. 16, 2004, and still pending); *Nystrom* v. *Trex Co., Inc.*, No. 03-1092 (Fed. Cir.) (petition for rehearing *en banc* filed July 26, 2004, and still pending). There is no reason for this Court to take a different approach.

[5] Petitioner's counsel of record in this Court also presented the oral argument for petitioner in the *Bayer III* appeal.

those issues were otherwise ripe for such review. In any event, the inequitable conduct proceedings make clear that this case provides no occasion for the Court to depart from its usual practices by, as petitioner suggests (Pet. 29-30), holding the present petition pending further developments in a different case in the court of appeals.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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